

## **REMARKS**

The Office Action mailed October 17, 2007 has been reviewed and the comments of the U.S. Patent and Trademark Office have been considered. Claims 1-9 are pending in this application. By this Amendment, claims 1-4 have been amended, and claims 5-9 have been added. The as-filed specification supports the amendments and new claims by at least page 4, lines 6-24, and by Figs. 1-2.

The drawings have been objected to because they purportedly do not show a "specimen removal space" recited in claim 1. Applicants respectfully traverse the objection. An example of the recited "specimen removal space" is currently shown, at least in part, in the drawings and labeled as number "9". The specification at page 4, line 9, states that the "needle unit 9 comprises, for example, a hollow needle ..." (emphasis added). Fig. 2 illustrates a structure with a hollow interior space. The specification at page 1, line 3, describes a "needle unit with specimen removal space". Accordingly, it is respectfully submitted that the drawings show the recited specimen removal space, and it is respectfully requested that the objection be withdrawn.

The Office Action at page 3 requires the submission of improved drawings. Formal drawings have been submitted with this Amendment. Accordingly, the Office's requirement has been satisfied. No new matter has been added.

The Office Action at pages 3-4 recommends that the specification be amended to include section titles. By this Amendment, the specification has been amended to address the Office's recommendations. A substitute specification is attached to this Amendment. No new matter has been added.

The Office Action at page 4 requires action in regard to an extra comma. By this Amendment, the specification has been amended to address the Office's requirement.

Claims 3 and 4 stand objected to because of informalities. By this Amendment, the claims have been amended to address the informalities. Accordingly, it is respectfully requested that the objection be withdrawn.

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, in regard to antecedent basis. By this Amendment, claim 4 has been amended. Accordingly, it is respectfully requested that the rejection be withdrawn.

Claim 1 stands rejected under 35 U.S.C. §103(a) over Haaga (US5718237) in view of Teo (US7156836); claim 2 stands rejected under 35 U.S.C. §103(a) over Haaga in view of Teo

and further in view of Carrillo (US2003/0088153); claim 3 stands rejected under 35 U.S.C. §103(a) over Haaga in view of Teo and Carrillo and further in view of Goldenberg (US6033369); and claim 4 stands rejected under 35 U.S.C. §103(a) over Haaga in view of Teo and further in view of Goldenberg. The rejections are respectfully traversed.

The applied references fail to show, describe, teach or suggest a coaxial cannula having a proximal end with a sealing element that seals a space between the inner wall of the coaxial cannula and an outer wall of a sample detaching device enclosed by the coaxial cannula, so that the sealing element releases air when the needle unit is inserted and prevents air from entering after the needle unit has been positioned and a vacuum has been created.

Haaga, Carrillo, and Goldenberg do not show or describe a sealing element that releases air from, or prevents air from entering, a space between a cannula and a device within the cannula. The Office acknowledges that Haaga fails to show or describe these features, and relies on the teachings of Teo to remedy the deficiencies of the primary reference, Haaga. Specifically, the Office relies on the following statement in Teo: "Furthermore, the inner and/or outer cannula may be provided with a one way valve, to prevent ingress or egress of fluid, depending on use." See Teo at col. 5, lines 57-60.

Teo, however, fails to show, describe, teach, or suggest the placement of a one-way valve at a proximal end or at any specific location on the inner or outer cannulas, or describe the one-way valve to prevent the ingress or egress of fluid from a space between the inner and outer cannulas. Rather, Teo teaches that a one-way valve can be used to prevent flow through the inner and/or outer cannulas as a whole, and not specifically for the teaching that the Office relies on in the rejection, i.e., the one-way flow in the space between the inner and outer cannulas.

Teo also teaches away from the interpretation of Teo applied by the Office. Teo teaches that there should not be fluid flow in the space between the inner and outer cannula so as to maintain a clean surface that reduces infection and clots. See Teo at col. 4, lines 38-49 and at Abstract. Teo at col. 3 (lines 22-24) teaches that there should be a tight sliding fit between the inner and outer cannulas "so as to prevent fluids [from] entering between the two sliding surfaces" of the inner and outer cannulas. Teo at col. 3 (lines 48-53) repeats that fluid flow should be prevented, i.e., "tight enough to prevent blood or other fluids from seeping in between the two surfaces" of the cannulas. Teo at col. 5 (lines 32-41) describes alternative embodiments that also prevent flow between the inner and outer cannulas.

Also, each time Teo describes the "relatively tight" space between the inner and outer cannulas, it is in regard to the prevention of fluid flow between the cannulas. The portion of Teo relied upon by the Office (col. 5, lines 57-60) thus does not teach that a fluid flows in the space, as asserted in the Office Action at page 7. The Office is required to consider the above-cited aspects of Teo that teach away from the claimed invention. *See* MPEP §2141.02(VI). However, this requirement has not been met by the explanation in the Office Action.

Furthermore, as explained above, Teo teaches that there should not be fluid flow in the space between the inner and outer cannulas so as maintain a clean surface that reduces infection and clots when the inner cannula is pulled out and replaced with a new inner cannula. *See* Teo at col. 4, lines 38-49. As Teo explains, stagnated and clotted blood are a potential source of infection. *See* Teo at col. 1, lines 28-29. Accordingly, the proposed modification of Teo to include a fluid containing space between the inner and outer cannulas would render the Teo device unsatisfactory for its intended purposed, contrary to MPEP §2143.01(V).

For the foregoing reasons, the applied references fail to show, describe, teach, or suggest all of the features recited in independent claim 1 or the dependent claims thereof. It is respectfully requested that the rejections be withdrawn.

With regard to new claims 5-9, the applied references fail to show, describe, teach, or suggest a cannula having a sealing element extending proximally from the proximal end of an outer tube to form a seal where an edge of the sealing element contacts an inner tube, or a method of venting a cannula involving forming a seal with a sealing element extending from a proximal end of an outer tube so that an edge of the sealing element is flexibly pressing against an outer surface of an inner tube slidably disposed within a lumen of the outer tube to form the seal.

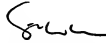
## CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this Application and the prompt allowance of at least the pending claims.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,



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